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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/369,016	08/05/99	FARMER S	GANEDEN-04(1

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EXAMINER	
KERR, J	
ART UNIT	**PAPER NUMBER**
1633	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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A - File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/369,016	FARMER, SEAN	
	Examiner	Art Unit	
	Janet Kerr	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-20 and 22-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-20, and 22-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Response to Amendment

Applicant's amendment, filed 9/29/00, has been entered.

Claims 2 and 21 have been canceled.

Claims 45-50 have been added.

Claims 1, 3-20, and 22-50 remain pending.

Claim Objections

Claims 23 and 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 23 and 24 define the bacteria of claim 20 as *Sporolactobacillus* or *Bifidiobacterium*, respectively. However, claim 20, upon which claims 23 and 24 depend, recites *Bacillus* as the requisite bacteria. Therefore, claims 23 and 24 do not further limit the subject matter of claim 20

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-20, and 22-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the following reasons: it is unclear if applicant is claiming a therapeutic composition or a composition as the phrase "therapeutic composition" has been bracketed, i.e., deleted, in the amendment; it is unclear why there is a period "." after the term "of" on line 7 of the claim.

Claim 3 is rendered vague and indefinite by the phrase "selected from a group comprising" as it is unclear if the claimed *Lactobacillus* bacteria which follow are intended to be elements of a Markush group or if other bacteria are encompassed in the claim. The metes and bounds of the claim are unclear. If applicant intended to limit the bacteria to those recited, then the claim should be amended to "selected from the group consisting of". Claim 3 is further rendered vague and indefinite by the phrase "any genetic variants thereof" as it is unclear from the specification and the claim what type of genetically variant bacteria are suitable for the therapeutic composition. The claim is also rendered vague and indefinite by the phrase "therapeutic composition" as it is unclear what type of therapy is intended. It is unclear if other components are required in the composition to render the composition "therapeutic".

Claims 4 and 5 are rendered vague and indefinite by the phrase "therapeutic composition" as it is unclear what type of therapy is intended. Thus, it is unclear if other components are required in the composition to render the composition "therapeutic".

Claim 6 is rendered vague and indefinite by the phrase "selected from a group consisting of" as it is unclear if the bacterial strains can be selected from other groups. If applicant intended only the recited strains, then the phrase should be amended to "selected from the group consisting of". Claim 6 is further rended vague and indefinite by the phrase "genetic variants thereof" as it is unclear from the specification and the claim what type of genetically variant bacteria are suitable for the composition.

Claim 7 is rendered vague and indefinite by the term "or" on line 3 as this is an improper term for Markush language. The "or" should be changed to "and" to overcome this rejection.

Claims 9, 10, 12, 15, 17, 28, 29, 31, 34, 36, 38, 42, 47, and 49 are rendered vague and indefinite by the term "preferably" because it is unclear whether the limitations following the term are part of the claimed invention. See MPEP § 2173.05(d).

Claim 9 is further rendered vague and indefinite for the following reasons: the phrase "wherein the total administered concentration of said composition" is confusing because there is no administration step in claim 6, i.e., the phrase lacks antecedent basis; and it is unclear as to

what "the concentration of said composition" refers, i.e., did applicant intend a specific weight of bacteria based on the total weight of the composition and if so, is the weight of bacteria wet weight or dry weight?

Claim 10 is rendered vague and indefinite by the phrase "wherein the total administered concentration of *Bacillus coagulans* within said composition" for the following reasons: there is no administration step in claim 6, and there is "concentration" recited in claim 6, i.e., there is no antecedent basis for the phrase. Moreover, the claimed numbers of bacteria or spores are listed as an amount (i.e., approximately $1x10^3$ to approximately $1x10^{12}$ viable bacteria or spores), not as a concentration (e.g., approximately $1x10^3$ to approximately $1x10^{12}$ viable bacteria or spores/gram of the total composition). The metes and bounds of the claim are not clear.

Claims 12 and 31 are rendered vague and indefinite by the phrases "The composition of claims 6 or 11, wherein said bifidogenic factor", as recited in claim 12, and "The composition of claims 25 or 30, wherein said bifidogenic factor", as recited in claim 31, as there is no bifidogenic factor recited in claim 6 or claim 25. The phrases lack antecedent basis.

Claims 13, 19, 20, 25, and 50 are rendered vague and indefinite by the phrase "selected from a group consisting of" as it is unclear if other bacteria not recited in the claims are included in the composition. If applicant intended to recite the claimed bacteria as a Markush group, then the phrase "selected from a group consisting of" should be changed to "selected from the group consisting of".

Claims 13 and 32 are rendered vague and indefinite by the phrase "said therapeutic composition" because the phrase lacks antecedent basis as there is no "therapeutic composition" recited in claim 6. The claims are also confusing because the locations of administration of the composition can be topical, vaginal, nasal, ocular and otic, yet claim 6 recites that the composition is for administration to the gastrointestinal tract. How does topical, vaginal, nasal, ocular and otic administration of the composition relate to the gastrointestinal tract and solubility and bioavailability of nutritional materials within the gastrointestinal tract?

Claim 15 is rendered vague and indefinite by the phrase "said therapeutic composition" because the phrase lacks antecedent basis as there is no "therapeutic composition" recited in claims 6 or 14.

Claim 19 is rendered vague and indefinite by the phrase "derived from" because it is unclear what type of derivation is required. It is suggested that applicant amends "derived from" to "obtained from".

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 9, 10, 12, 17, 28, 29, 31, 34, and 36 recite both broad and narrow concentrations for individual vitamins and minerals.

Claims 13 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of the claimed probiotic compositions buccally, does not reasonably provide enablement for administration of the claimed probiotic compositions topically, vaginally, nasally, ocularly or otically. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

The claims are directed to a priobiotic microbial composition and a method of administering a probiotic microbial composition wherein the location of administration is selected from buccal, topical, vaginal, nasal, ocular, and otic administration locations.

While the specification is enabling for buccal administration, the specification is non-enabling for topical, vaginal, nasal, ocular, and otic administration locations. The specification does not provide sufficient guidance with respect to the amount of probiotic to administer topically, vaginally, nasally, ocularly or otically such that upon administration, the probiotic increases the solubility and bioavailability of nutritional materials within the gastrointestinal tract. Moreover, the specification does not provide guidance with respect to the appropriate pharmaceutical carriers suitable for administration to the claimed locations, and wherein the pharmaceutical carriers also have the characteristic of being suitable for administration to the gastrointestinal tract of a vertebrate. In addition, the prior art fails to teach administration of the probiotic at the claim-designated locations. As the probiotics are required to be active in the gastrointestinal tract, it is not readily apparent from the specification how administration of the probiotic, other than buccally, will effectively result in increasing the solubility and bioavailability of nutritional materials within the gastrointestinal tract.

In view of the lack of guidance in the specification, the lack of working examples, and the lack of teaching in the prior art of administering probiotics at topical, vaginal, nasal, ocular, and otic administration locations, one of skill in the art could not practice the claimed method with the claimed composition commensurate in scope with the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-14, 16, 20, 22, 24-33, 35, 38-44, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Cavadini *et al.* (U.S. Patent No. 5,968,569, 10/19/99, effective filing date of 12/23/97, newly applied).

Cavadini *et al.* teach a probiotic microorganism composition comprising a non-pathogenic, lactic acid-producing bacteria in a pharmaceutically acceptable carrier suitable for administration to the gastrointestinal tract of a vertebrate wherein the bacteria can be selected from 1) the genera Bacillus, and species *Bacillus coagulans*, *Bacillus licheniformis*, or *Bacillus subtilis*, 2) or the genera, Bifidobacterium, and the species *Bifidobacterium bifidum*, *Bifidobacterium infantis*, or *Bifidobacterium longum*, 3) or the genera, Lactobacillus, and the species *Lactobacillus acidophilus*, *Lactobacillus alimentarius*, *Lactobacillus casei*, subsp. *casei*, *Lactobacillus casei* Shirota, *Lactobacillus curvatus*, *Lactobacillus delbruckii* subsp. *lactis*, *Lactobacillus farciminus*, *Lactobacillus gasseri*, *Latobacillus helveticus*, *Lactobacillus johnsonii*, *Lactobacillus reuteri*, *Lactobacillus rhamnosus* (Lactobacillus GG), and *Lactobacillus sake* (see column 2, line 60 through column 3, line 33, and Examples 1, 2, and 7). The probiotic microorganisms are preferably in powdered, dried form, especially in spore form, and the microorganisms can be encapsulated in a sugar, fat or polysaccharide matrix to further increase the probability of survival (see column 3, lines 28-33). The composition can also include vitamins and minerals, protein sources, sources of insoluble fiber such as wheat bran, corn bran, rice bran, rye bran, sources of soluble fiber such as chicory fibers, inulin, fructooligosaccharides (which are bifidogenic factors), soy oligosaccharides, oat bran concentrate, etc. The maximum level of soluble fiber is preferably about 20% by weight (see, e.g., column 3, line 56 through column 4, line 11). Note that by including protein sources and fiber sources in the composition (which inherently contain vitamins

and minerals), the composition necessarily contains at least one of the claim-designated vitamins and minerals barring evidence to the contrary. The addition of vitamins C and E, and trace elements is also contemplated (see, e.g., column 5, lines 29-36). The composition can contain about 10^4 to about 10^{10} cells of the probiotic microorganism per gram of the composition or about 0.5% to about 20% by weight of the mixture of the probiotic microorganism and carrier substrate (see, e.g., column 6, lines 9-16). Cavadini *et al.* also teach that when consumed in adequate amounts, the composition results in a production of acids, such as lactic acid and acetic acid in the gut of the human or animal. This inhibits the growth of pathogenic bacteria such as *Clostridium perfringens* or those which adversely affect well being, and has a beneficial effect on the human or animal (see, e.g., column 6, lines 55-67). The amount of the composition consumed to obtain a beneficial effect is dependent on the size and age of the consumer; an adequate daily amount is considered to be about 10^6 to about 10^{12} cells of the microorganism. Cavadini *et al.* also teach administration of a composition comprising *Bacillus coagulans* or *Lactobacillus johnsonii* (see, e.g., Examples 5 and 9). The oral administration of these microorganisms inherently results in an increase in solubility and bioavailability of nutritional materials within the gastrointestinal tract of a vertebrate, and the probiotic activity is inherently due to vegetative growth and an extracellular product produced by the microorganisms barring evidence to the contrary. Moreover, as there are no distinguishing features between the claimed microorganisms and the reference microorganisms, the claim-designated properties of the microorganisms are also inherent to the reference microorganisms barring evidence to the contrary.

As Cavadini *et al.* teach all of the elements of the claimed invention, the claimed invention is anticipated by Cavadini *et al.*

Claims 1, 3, 5-17, 20, 22, 24-36, 38-44 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Langrehr (U.S. Patent No. 5,785,990, 7/28/88, effective filing date of 7/10/95, newly applied).

Langrehr teaches a probiotic composition and method of administering the composition wherein the composition comprises less than about 1.0% microbials selected from the group consisting of *Bacillus coagulans*, *Bacillus licheniformis*, *Bacillus subtilis*, *Bifidobacterium bifidum*, *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus lactis*, *Streptococcus diacetylactis*, and mixtures thereof; fructooligosaccharides at less than about 2.0% by weight; about 0.1-0.4% by weight of a vitamin D ingredient wherein the vitamin D concentration is approximately 15,000,000 IU/lb of the ingredient; about 0.3-1.4% by weight of a vitamin A ingredient, wherein the concentration of vitamin A is approximately 7,562,000 IU/lb of the ingredient; about 0.8-3.4% by weight of a vitamin E ingredient, whrein the concentration of vitamin E is approximately 60,000 IU/lb of the ingredient; electrolytes, at less than about 2.5% by weight, wherein the electrolytes are selected from salts of sodium, magnesium, potassium, calcium, and combinations thereof; about 2.5-10% by weight micronutrients, wherein the micronutrients are selected from cobalt, copper, iodine, iron, magnesium, manganese, selenium, zinc, choline chloride, vitamin C, niacin, d-pantothenic acid, riboflavin, thiamine, menadione dimethylpyrimidinol bisulfite, pyridoxine, folic acid, vitamin E, vitamin A, vitamin D, vitamin B12, biotin, biocompatible salts thereof and mixtures thereof (see, e.g., column 3, lines 20-64, column 4, line 48 to column 5, line 24, Tables 1-4, and claims 1-7). The oral administration of the microorganisms in the composition inherently results in an increase in solubility and bioavailability of nutritional materials within the gastrointestinal tract of a vertebrate, and the probiotic activity is inherently due to vegetative growth and an extracellular product produced by the microorganisms barring evidence to the contrary. Moreover, as there are no distinguishing features between the claimed microorganisms and the reference microorganisms, the claim-designated properties of the microorganisms are also inherent to the reference microorganisms barring evidence to the contrary.

Thus, the teachings of Langrehr anticipate the claimed invention.

Claims 4, 23, 45, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Delespaul *et al.* (U.S. Patent No. 5,520,936, 1996, newly applied).

Delespaul *et al.* teach a composition, i.e., a microbial food additive, for human consumption comprising the microorganism, Sporolactobacillus P44, or the microorganism, *Sporolactobacillus inulinus*. The microorganisms are provided in the form of natural spores in a pharmaceutically acceptable carrier, and are useful as bioregulators of lactose and enhance the digestive capacity of the small intestine (see, e.g., column 1, line 14 through column 3, line 15). Delespaul *et al.* also teach administration of the microorganisms to a vertebrate (see, e.g., Example 3). The microorganisms are inherently lactic acid producing bacteria which increase the solubility and bioavailability of nutritional materials within the gastrointestinal tract of a vertebrate, and administration of the composition, which is taught by Delespaul *et al.*, inherently results in an increase in the solubility and bioavailability of nutritional materials within the gastrointestinal tract of a vertebrate barring evidence to the contrary.

Thus, the teachings of Delespaul *et al.* anticipate the claimed invention.

Claims 1, 3, 6-10, 13, 19, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Hata (U.S. Patent No. 4,210,672, 1980, newly applied).

Hata teaches a composition comprising *Lactobacilus thermophilus* (which can be considered a genetic variant of any of the claim-designated Lactobacillus species), and which is also known as *Bacillus coagulans*, and a pharmaceutically acceptable carrier, i.e., yogurt (see, e.g., column 1, lines 10-25, column 2, lines 19-35, and line 54 through column 3, line 18, Examples 1 and 2, and claims 1-3). As the spores germinate to produce yogurt, the yogurt inherently comprises the extracellular supernatant obtained from culturing the microorganism. As there are no distinguishing features between the claimed microorganisms and the reference microorganisms, the reference microorganisms are inherently lactic acid producing bacteria which increase the solubility and bioavailability of nutritional materials within the gastrointestinal tract of a vertebrate barring evidence to the contrary. Moreover, as there are no distinguishing features

between the claimed microorganisms and the reference microorganisms, the claim-designated properties of the microorganisms are also inherent to the reference microorganisms barring evidence to the contrary.

Thus, the teachings of Hata anticipate the claimed invention.

Claims 6, 18, 25, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreuzer (Agribiol. Res., 47:13-23, 1994, newly applied).

Kreuzer teaches a composition and method of administering the composition wherein the composition comprises the probiotic BioPlus 2B which contains *Bacillus licheniformis* and *Bacillus subtilis* (which can be considered genetic variants of *Bacillus coagulans*), and the antibiotic, Carbadox (see, e.g., pages 13-14, under "Materials and Methods"). As there are no distinguishing features between the claimed microorganisms and the reference microorganisms, i.e., there is no disclosure in the specification as to what genetic variants of *Bacillus coagulans* encompass, the reference microorganisms are inherently lactic acid producing bacteria which increase the solubility and bioavailability of nutritional materials within the gastrointestinal tract of a vertebrate barring evidence to the contrary. Moreover, as there are no distinguishing features between the claimed microorganisms and the reference microorganisms, the claim-designated properties of the microorganisms are also inherent to the reference microorganisms barring evidence to the contrary.

Thus, the teachings of Kreuzer anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 14-17, 25, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaull (U.S. Patent No. 4,751,085, 1988) taken with Hata (U.S. Patent No. 4,210,672, 1980).

Hata teaches a composition comprising *Lactobacilus thermophilus* (which can be considered a genetic variant of any of the claim-designated Lactobacillus species), and which is also known as *Bacillus coagulans*, and a pharmaceutically acceptable carrier, i.e., yogurt (see, e.g., column 1, lines 10-25, column 2, lines 19-35, and line 54 through column 3, line 18, Examples 1 and 2, and claims 1-3). As there are no distinguishing features between the claimed microorganisms and the reference microorganisms, the reference microorganisms are inherently lactic acid producing bacteria which increase the solubility and bioavailability of nutritional materials within the gastrointestinal tract of a vertebrate barring evidence to the contrary. Moreover, as there are no distinguishing features between the claimed microorganisms and the reference microorganisms, the claim-designated properties of the microorganisms are also inherent to the reference microorganisms barring evidence to the contrary.

Hata does not disclose supplementing the yogurt composition with one or more of the claim-designated vitamins and minerals in the claim-designated amounts. However, Gaull teaches compositions comprising yogurt and the claim-designated vitamins and minerals in the claim designated amounts (see, e.g., column 1, lines 10-15, Examples 1-5, column 6 line 46 through column 8, line 6). Thus, combining yogurt with vitamins and minerals would have been obvious to one of ordinary skill in the art in view of the teachings of Gaull.

It would have been obvious to one of ordinary skill in the art at the time of filing to modify the *Bacillus coagulans* yogurt composition of Hata by including in the composition appropriate amounts of vitamins and minerals, as taught by Gaull, in view of the teachings of Gaull that yogurt provides a suitable excipient for the vitamin and mineral composition which, in and of itself, may have a nutritional benefit (see column 7, lines 7-18). Thus, one of skill in the art would have had a high expectation of successfully supplementing the composition of Hata, which increases

solubility and bioavailability of nutrients, with the vitamins and minerals taught by Gaull, to provide a composition which has improved nutritional properties, and to administer the composition to a vertebrate, barring evidence to the contrary.

Thus the claimed invention as a whole was clearly *prima facie* obvious at the time the claimed invention was made especially in the absence of sufficient, clear, and convincing evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1633, at (703) 305-4051. Any administrative or procedural questions should be directed to Kimberly Davis, Patent Analyst, at (703) 305-3015. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

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